

Project BREATHE: Better Respiratory Equipment utilizing Advanced Technologies for Healthcare Employees

Debra Novak¹, Raymond Roberge¹, Ziqing Zhuang¹, Stacey Benson², Ronald Shaffer¹

¹CDC/NIOSH/NPPTL, Pittsburgh, PA, ²URS Corp, Pittsburgh, PA

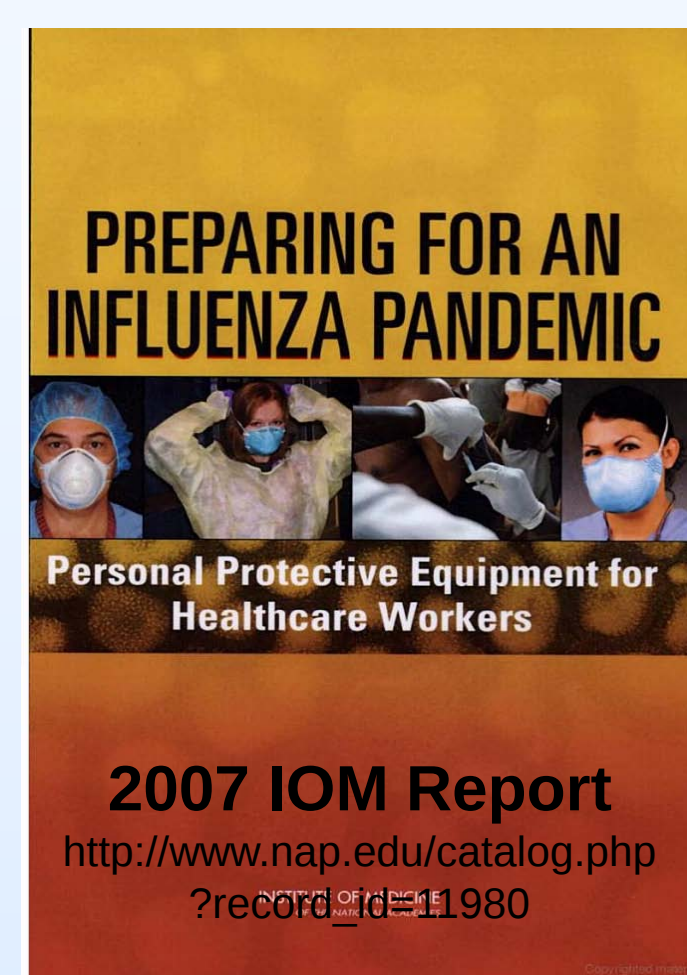
Objective

To improve respirator use compliance among healthcare workers (HCW) by developing information products, respirator performance requirements, and advanced technologies for the next generation of HCW respirators that are more comfortable and tolerable.



Background

- Respiratory protection is an essential component of infection prevention and occupational health programs to minimize exposure to droplet and airborne-spread pathogens during routine care and mass casualty events
- Failure to properly use respirators has been identified as a possible cause of patient-to-HCW transmission of infection
- Compliance with recommended use of respiratory protection has been found to be below 60% in various clinical settings
- Non-compliance has been linked to heat, sweating, facial pressure, breathing resistance, anxiety and communication difficulties
- Institute of Medicine (IOM) recommended increased research on the design and engineering of the next generation of respirators for HCWs that would enhance their safety, tolerability and comfort



Key Partners

- Veterans Health Administration (VHA)
- Association for Professionals in Infection Control and Epidemiology (APIC)
- American Nursing Association (ANA)
- The Joint Commission (TJC)
- Respirator Manufacturers (RM)
- Johns Hopkins University (JHU)
- Centers for Disease Control and Prevention (CDC)
- Association of periOperative Registered Nurses (AORN)
- Association of Occupational Health Professionals in Healthcare (AOHP)
- Texas Tech University (TTU)

Project Scope

Phase 1: Interagency Working Group

Phase 2a: Improving HCW compliance with N95 FFR use (NPPTL, Professional Organizations)

Phase 2b: Comfort and tolerability research and test method development (NPPTL, TTU)

Phase 2c: Respirator clinical effectiveness study (VHA, CDC, JHU)

Phase 2d: Partnership development / prototype development (VHA, RM)

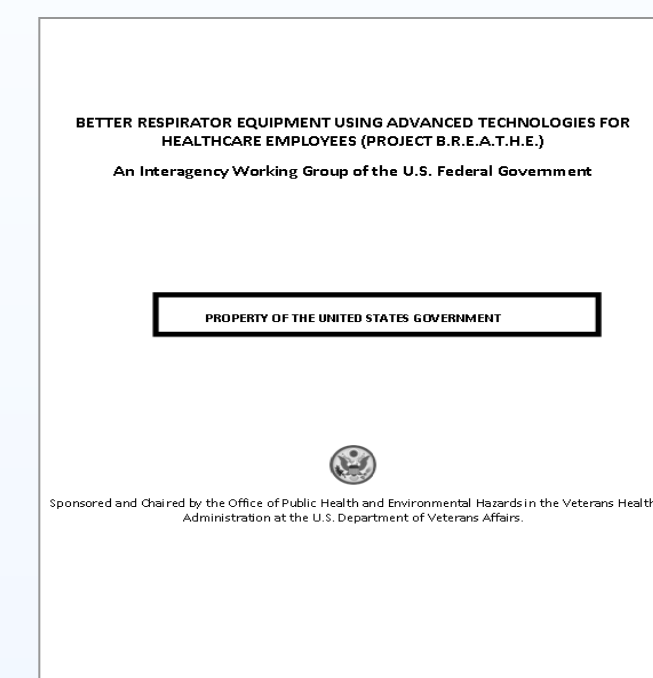
Phase 3: Prototype benchmark (NPPTL) and field trials (VHA)

Phase 4: Commercialization / standards development (VHA, RM)

Project BREATHE Interagency Working Group (Phase 1) - Completed

A working group, consisting of nine federal departments and agencies, was assembled. The working group was co-chaired by staff from the VHA and NPPTL. A consensus was reached for 28 desirable characteristics that fell into one of four categories:

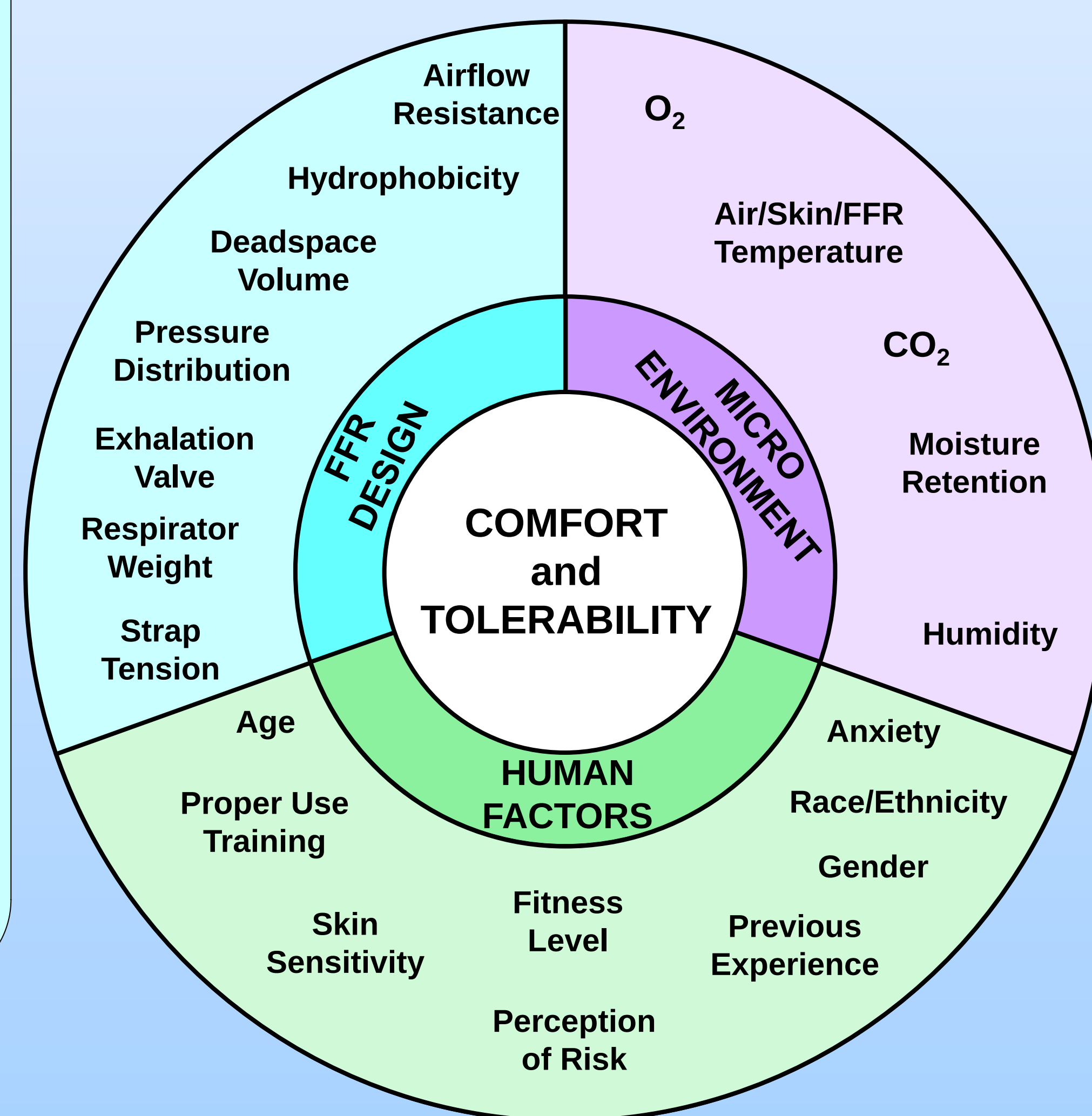
- Respirators should perform their intended functions effectively and safely
- Respirators should support, not interfere with, occupational activities
- Respirators should be comfortable and tolerable for the duration of wear
- Respiratory protection programs comply with federal standards and guidelines, state regulations and local policies



Conceptual Framework for NPPTL Projects (Phase 2a, b) – In Progress

Overview: The diagram below depicts the major concepts (inner circle) and variables (outer circle) that will be examined through proposed comfort and tolerability research projects at NPPTL.

NPPTL has partnered with TTU to generate computer models, using the NIOSH headforms to explore how FFR strap location, orientation and tension impact contact pressure, contact area and fit. NPPTL will collect data on some of these variables in human subject testing.



NPPTL will measure characteristics of the FFR microenvironment during human subject treadmill tests. Thermal images will also be captured.

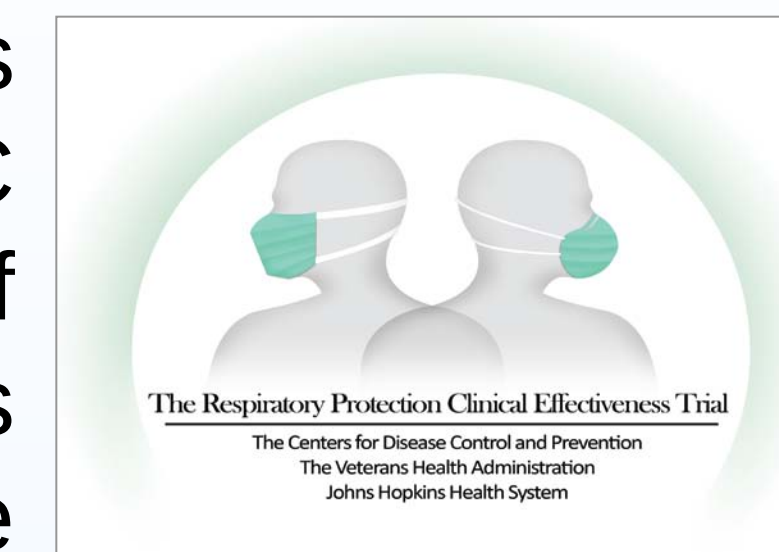
Subjective measures of comfort and tolerability will be collected during treadmill testing.

NPPTL is collaborating with key healthcare professional organizations (TJC, AORN, AOHP, APIC, ANA) to identify informational strategies to reinforce the proper use of FFRs.

Carbon dioxide inhalation tests will be conducted to determine potential anxiety associated with respirator use. Skin sensitivity and previous respirator experience will be assessed in human subject tests.

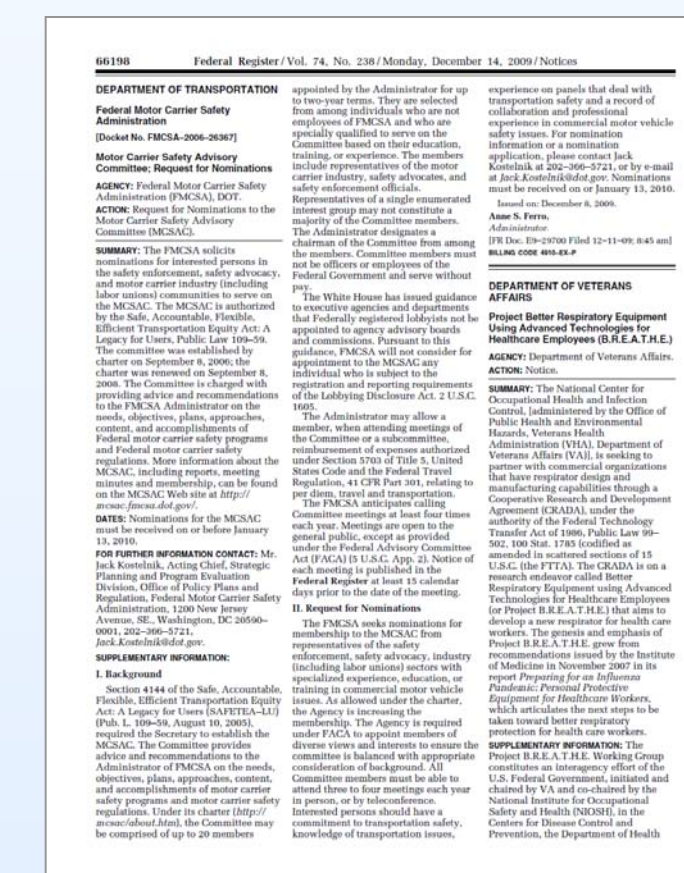
Concurrent Projects (Phase 2c, d) – In Progress

A respirator clinical effectiveness study is proposed as a joint collaboration of the CDC (including NPPTL), JHU and VHA, to determine if the incidence of respiratory viral infections is lower among HCWs who care for patients while wearing respirators versus those who wear surgical masks or “usual protective measures”. A protocol has been drafted and is under review.



The VHA has published a Federal Register Notice announcing partnership opportunities. The VA will initiate partnership with at least 2 manufacturers to develop the Project BREATHE prototype respirator. Field testing of the resulting prototype respirators will be conducted and include feedback from HCWs.

<http://frwebgate.access.gpo.gov/cgi-bin/getpage.cgi>



Future Work (Phases 3 and 4)

The results obtained during phase 2 will be incorporated into the creation of a prototype respirator, designed to meet the specific needs of HCWs. Phase 3 benchmark testing will be conducted by NPPTL and field testing will be conducted by VHA. Once prototype testing is complete, the commercialization of the new respirator and standards development will begin (phase 4).

Expected Outcomes

- Manufacturers use the Project BREATHE final report, test methods, and prototype designs to develop HCW-specific respirators that provide increased safety, comfort, tolerability, and wearability
- Government agencies and standards development organizations use project information to develop guidance documents and recommendations to improve the use of respirators by HCW
- Future revisions to 42 CFR Part 84 use test methods and performance requirements developed in this project

Timeline

- Phase 1: 2008 – 2009
- Phase 2a: 2010 – 2012
- Phase 2b: 2010 – 2012
- Phase 2c: 2010 – 2013
- Phase 2d: 2010 – 2012
- Phase 3: 2011 – 2013
- Phase 4: 2014

Disclaimer: The findings and conclusions of this poster have not been formally disseminated by the National Institute for Occupational Safety and Health and should not be construed to represent any agency determination or policy.